IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

BUZZIE SMITH, individually and on behalf of the Heirs and Estate of Charles A. Smith, Deceased, Plaintiff, v. TERUMO CARDIOVASCULAR SYSTEMS CORPORATION; IHC HEALTH SERVICES, INC.; INTERMOUNTAIN MEDICAL CENTER; INTERMOUNTAIN HEALTH CARE, INC., Defendants.	**SEALED MEMORANDUM DECISION AND ORDER GRANTING/DENYING [158] MOTION TO EXCLUDE RICHARD IMBRUCE** Case No. 2:12-cv-00998-DN District Judge David Nuffer

The general facts in this case are now quite familiar. The decedent Charles A. Smith (Mr. Smith), represented in this litigation by Buzzie Smith (Mrs. Smith), underwent surgery on his heart in September 2010. There were complications during the surgery. Eleven months later, Mr. Smith passed away. Mrs. Smith brings this action against the hospital (IHC) where Mr. Smith underwent the surgery and the manufacturer (Terumo) of a device used during the surgery (collectively "Defendants").[1]

IHC offers the expert opinion of Dr. Richard Imbruce to prove that the complications that occurred during surgery were software- and not user-based. In this motion, Terumo moves (Motion) to exclude Dr. Imbruce from testifying.[2] Terumo argues that Dr. Imbruce is not

[1] Amended Complaint, docket no. 17, filed October 7, 2013.

[2] Terumo Cardiovascular Systems Corporation's Motion to Exclude Richard Imbruce (Motion), docket no. 158, filed under seal May 15, 2017.

qualified to testify and, in the alternative, his opinion is not reliable. IHC opposes (Opposition) the motion.[3] Terumo replies (Reply) in support of the motion.[4]

Dr. Imbruce is not qualified to offer the opinions in his report. And his opinion is unreliable. Therefore, the Motion is GRANTED.

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PRELIMINARY ISSUES

1. IHC will not be sanctioned for drafting Dr. Imbruce's report.

Terumo argues that Dr. Imbruce's should be excluded because he did not prepare his report in compliance with Federal Rule of Civil Procedure 26. Dr. Imbruce and IHC acknowledge that Dr. Imbruce did not draft his expert report.[5]

Federal Rule of Civil Procedure 26(a)(2)(B) states that the expert must "prepare" the report accompanying the disclosure of expert testimony.

Of course, the better practice is for experts to prepare, draft and write their own reports. Even so, if the report was physically drafted by some other person, it still passes muster if it

[3] Intermountain Medical Center's Memorandum in Opposition to Terumo's Motion to Exclude Richard Imbruce (Opposition), docket no. 184, filed under seal June 13, 2017.

[4] Terumo Cardiovascular Systems Corporation's Reply in Support of Its Motion to Exclude Richard Imbruce (Reply), docket no. 198, filed June 20, 2017.

[5] Deposition of Richard Imbruce (Imbruce Deposition) at 123:14–21, docket no. 158, filed under seal May 15, 2017; Opposition at 27–31.

represents the expert's actual opinion.[6] The threat of sanctions to both counsel and expert for making false representations to the court sufficiently militates against submitting a fraudulent report. Indeed, the crucible of deposition and trial (*i.e.*, the expert testifying under oath and being subject to examination) should eliminate any incentive for counsel to misrepresent an expert's opinion.

Therefore, Dr. Imbruce's opinion will not be considered less credible or excluded simply because counsel drafted it. However, IHC is strongly encouraged to adopt a different practice in the future.

2. Dr. Imbruce's affidavit will not be considered.

IHC attaches to its Opposition an affidavit from Dr. Imbruce (Imbruce Affidavit).[7] In his affidavit, Dr. Imbruce shores up his credentials,[8] reiterates his conclusions and their bases,[9] and outlines the process for preparing his opinion and eventual report.[10] The deadline for IHC to make expert disclosures was November 28, 2016.[11] IHC did not file Dr. Imbruce's Affidavit until June 13, 2017. Terumo argues that it should therefore be "stricken and ignored."[12]

Federal Rule of Civil Procedure 26(a)(2)(D) states that a "party must make [the expert disclosures, including the report] at the times and in the sequence that the court orders." Federal Rule of Civil Procedure 26(e)(1)(A) states that a party must file a supplemental report if "in some material respect the disclosure or response is incomplete or incorrect, and if the additional

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[6] *See U.S. v. Kalymon*, 541 F.3d 624, 638 (6th Cir. 2008) ("A party's attorney can reduce an expert's oral opinion to writing so long as the report reflects the actual views of the expert.").

[7] Affidavit of Richard Imbruce, Ph.D (Imbruce Affidavit), docket no. 184-13, filed under seal June 13, 2017.

[8] *Id.* ¶¶ 1–12.

[9] *Id.* ¶¶ 13–17.

[10] *Id.* ¶¶ 18–34.

[11] Third Amended Scheduling Order at 1, docket no. 129, filed September 22, 2016.

[12] Reply at 3.

or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Courts have held that failure to timely file the expert disclosures and reports is sufficient grounds for excluding the report.[13]

Dr. Imbruce's Affidavit is excluded. It is not the type of supplemental report contemplated in Rule 26(e). IHC is simply providing it to bolster Dr. Imbruce's opinion. And further, it is mostly redundant; it merely confirms what Dr. Imbruce said in his original report.

BACKGROUND[14]

On September 13, 2010, Mr. Smith underwent heart valve replacement surgery (September 2010 surgery).[15] As part of the surgery, a Terumo Advanced Perfusion System 1 heart/lung bypass machine (System 1) was used.[16] The System 1 was to provide for the circulation of blood and oxygen through Mr. Smith's body while surgery was being performed on his heart valve.[17] At some point, the System 1 stopped working for 10–11 minutes.[18] Eleven months after his surgery, on August 6, 2011, Mr. Smith passed away from a myocardial infarction, (*i.e.*, heart attack).[19]

Dr. Imbruce offers the following opinion:

> Based on the materials I have reviewed, and based upon my training, education, and experience, it is my opinion that the failure of forward arterial flow from the System 1 cardiovascular bypass machine which occurred at the point of attempting bypass during the Charles Smith surgery on September 13, 2010, was

[13] *See, e.g.*, *Corwin v. Walt Disney Co.*, 475 F.3d 1239, 1252 (10th Cir. 2007).

[14] As specified in the other decisions regarding motions to limit and exclude in this case, the undisputed material facts will be determined in the rulings on the motions for summary judgment. The facts described below are provided only for context and are taken as alleged in the Complaint.

[15] Complaint ¶ 11.

[16] *Id.* ¶ 12.

[17] *Id.* ¶ 13.

[18] *Id.* ¶¶ 15–17; although the Complaint fails to specify how many minutes the bypass machine was not working, the parties seem to agree on between 10 and 11 minutes.

[19] *Id.*

> more likely than not caused by a flaw in the software operating system on the machine which was triggered by the occurrence of the air bubble alarm and the operator's effort to adjust the speed of the centrifugal pump drive motor.[20]

Dr. Imbruce arrived at this conclusion through failure analysis. According to Dr. Imbruce, failure analysis "is an engineering technique used to identify the cause of failure in a device."[21] It "involves identifying potential causes of a particular failure and then determining whether the potential cause is a viable explanation for the failure."[22] Dr. Imbruce lists five causes that, for him, compose the universe of possible causes. They include the following:

a. An upstream occlusion of the flow sufficient to overcome the pressure generated by the centrifugal pump head;
b. Sufficient air in the centrifugal pump head to decrease its capacity to generate pressure at a level able to overcome gravity and patient physiologic pressures;
c. Mechanical failure of the pump head such that it is unable to generate sufficient pressure for forward flow;
d. Malposition of the pump head and pump motor such that the rotary action of the pump motor is not effectively transferred to the pump head mechanism; and
e. Mechanical failure of the pump motor or lack of electrical power to the pump motor.[23]

After walking through the evidence, Dr. Imbruce determined that the "evidence does not support the conclusion that any of the typical causes of failed forward flow [listed above] occurred in the Smith case."[24] This leads Dr. Imbruce to conclude that "it is more likely than not that a software fault, the remaining potential cause of failure flow, was the cause of the failure of flow during the Smith procedure."[25]

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[20] Expert report of Richard Imbruce (Imbruce Report) at 1, docket no. 184-11, filed under seal June 13, 2017.

[21] *Id.* ¶ 13 at 3.

[22] *Id.*

[23] *Id.* ¶ 15 at 3.

[24] *Id.* ¶ 17 at 3.

[25] *Id.* ¶ 18 at 3.

DISCUSSION

Terumo argues the Dr. Imbruce's opinion should be excluded for two overarching reasons. First, Terumo argues that Dr. Imbruce is not "qualified to testify regarding failure analysis and the alleged product defects in the System 1."[26] Second, Terumo argues that Dr. Imbruce "failed to reliably apply his chosen methodology."[27]

Federal Rule of Evidence 702 addresses the standard for the admissibility of expert testimony.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.[28]

"Under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."[29] The inquiry of scientific reliability is flexible and focuses on principles and methodology.[30] The Supreme Court has offered several non-exhaustive factors that a court may rely on for determining reliability such as, whether the testimony can be tested, has been peer reviewed, has a known or potential rate of error, and has attracted acceptance in the relevant scientific community.[31]

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[26] Motion at 7.

[27] *Id.* at 13.

[28] Fed. R. Evid. 702

[29] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

[30] *See Id.* at 595

[31] *See Id.*

District courts serve as the gatekeepers of expert evidence, and must therefore decide which experts may testify and present evidence before the jury.[32] Courts are given "broad latitude" in deciding "how to determine reliability" and in making the "ultimate reliability determination."[33] The Federal Rules of Evidence, however, generally favor the admissibility of expert testimony.[34] Excluding expert testimony is the exception rather than the rule,[35] and often times the appropriate means of attacking shaky but admissible evidence is through vigorous cross-examination, and the presentation of contrary evidence.[36] "[T]he Federal Rules of Evidence favor the admissibility of expert testimony, and [courts'] role as gatekeeper is not intended to serve as a replacement for the adversary system."[37]

The inquiry into whether an expert's testimony is reliable is not whether the expert has a general expertise in the relevant field, but whether the expert has sufficient specialized knowledge to assist jurors in deciding the particular issues before the court.[38]

Expert testimony is subject to Federal Rule of Evidence 403. "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[39]

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[32] *See Id.* at 579.

[33] *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999), (citing *General Electric Co. v. Joiner*, 522 U.S. 135 (1997)).

[34] *See Daubert*, 509 U.S. at 588.

[35] *See* Fed. R. Evid. 702 Advisory Notes.

[36] *See Daubert*, 509 U.S. at 596.

[37] *THOIP v. Walt Disney Co.*, 690 F. Supp. 2d 218, 230 (S.D.N.Y. 2010).

[38] *Kumho*, 526 U.S. at 156.

[39] Fed. R. Evid. 403.

In determining whether expert testimony is admissible the first step is to determine whether the expert is qualified, and then if the expert is qualified determine whether the expert's opinion is reliable by assessing the underlying reasoning and methodology.[40] If the expert is qualified and the opinion reliable, the subject of the opinion must be relevant; i.e. the opinion must "help the trier of fact to understand the evidence or to determine a fact *in issue*."[41] "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."[42]

1. Dr. Imbruce is not qualified to testify regarding failure analysis and the alleged product defects in the System 1.

Terumo acknowledges that Dr. Imbruce "may be qualified to testify regarding certain medical devices."[43] But it argues that he is

> not qualified to testify regarding the cause of the lack of forward flow during Mr. Smith's surgery or the design and function of a perfusion machine such as the System 1 . . . [because] Dr. Imbruce is not a perfusionist, has never designed or used a perfusion machines [sic] such as the System 1, and he has no training or expertise in the areas of cardiopulmonary bypass."[44]

Terumo also argues that Dr. Imbruce "lacks the experience necessary to provide an academically grounded failure analysis of the lack of forward flow while Mr. Garrett [the perfusionist for Mr. Smith's surgery] used System 1."[45]

Dr. Imbruce received his BS, MS, and Ph.D. in biology.[46] Dr. Imbruce has in various capacities been involved in the health care profession since 1967.[47] Between 1968 and 1983, Dr.

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[40] *U.S. v. Nacchio*, 555 F.3d 1234, 1241(10th Cir. 2009).

[41] Fed. R. Evid. 702 (emphasis added).

[42] *Daubert*, 509 U.S. at 591.

[43] Motion at 8.

[44] *Id.*

[45] *Id.* at 11.

[46] Curriculum Vitae attached to Imbruce Report at 2, docket no. 184-11, filed under seal June 13, 2017.

[47] *Id.*

Imbruce was active as a researcher in areas related to breathing.[48] Between 1970 through 1981, he worked at the Norwalk Hospital as a clinical physiologist and director of the pulmonary function lab.[49] From 1981 to the present, Dr. Imbruce has worked in selling, marketing, and developing medical devices.[50]

IHC states that the "[m]ost pertinent" component of Dr. Imbruce's background for determining whether he is qualified is his "significant and substantial work experience in designing and developing medical devices and in troubleshooting malfunctions or problems in such devices."[51] In his deposition, Dr. Imbruce lists the equipment he developed:

> Lung function testing instruments that measure lung volumes, how gases move in the lung; exercise physiology equipment to do oxygen consumption, carbon dioxide production, exercise performance; cardiopulmonary stress-testing performance instruments; a nasogastric tube with an esophogeal balloon, which is a catheter which enters the esophagus and makes measurements and removes stomach contents; and a portable chemical oxygen generator which produces oxygen with chemical reaction with chemical powders.[52]

Dr. Imbruce's education, training, and experience do not show that he is qualified to testify regarding the lack of forward flow during Mr. Smith's surgery or the design and function of a perfusion machine such as the System 1. Dr. Imbruce never developed a perfusion machine.[53] Dr. Imbruce has not seen a System 1.[54] Dr. Imbruce has not operated a System 1.[55] Dr. Imbruce has not had the operation of a System 1 demonstrated for him.[56] Dr. Imbruce has not

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[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] Opposition at 21.

[52] Imbruce Deposition at 7:20–8:5.

[53] *Id.* at 12:10–13:22.

[54] *Id.* at 125:4–5.

[55] *Id.* at 125:6–7.

[56] *Id.* at 125:8–9.

witnessed a heart-lung bypass machine of any make or model operate within the last 20 years.[57] However, he has been involved in the development of a CO2 analyzer and oxygenator, both components of a perfusion device.[58] Terumo asked Dr. Imbruce what would happen if there were a software flaw in a perfusion device:

> Q. . . . What is the consequence of the software flaw?
> A. In that you are unable to translate your will to the device.
> Q. And so is the consequence in that circumstance in your opinion then that the machine remains at 1,500 rpms despite the manual input of the operator?
> A. I don't know what occurs.
> Q. Okay.
> A. But it's an inability of manual override of an automatic function.[59]

Dr. Imbruce's education, training and experience do not show that he is qualified to do a proper failure analysis. Dr. Imbruce defines failure analysis as "an engineering technique used to identify the cause of failure in a device."[60] Failure analysis, according to Dr. Imbruce, "involves identifying potential causes of a particular failure and then determining whether the potential cause is a viable explanation for the failure."[61] Dr. Imbruce admits that he has no training as an engineer.[62] Dr. Imbruce has never authored reports, texts, or articles relating to failure analysis. There is no indication in his curriculum vitae that he has any experience in failure analysis.[63]

Dr. Imbruce is not qualified to testify regarding the cause of the lack of forward flow in the System 1 and he is not qualified to do a failure analysis. His knowledge is too general. And

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[57] *Id.* at 125:20–24.

[58] *Id.* at 117:5–117:23.

[59] *Id.* at 149:13–24.

[60] Imbruce Report ¶ 13 at 3.

[61] *Id.*

[62] Imbruce Deposition at 119:5–15.

[63] And even if the affidavit were included, Dr. Imbruce does not demonstrate with any detail that he is qualified to do failure analysis. *See* Imbruce Affidavit ¶ 14 at 4–5.

here the question is "specific, not general."[64] Dr. Imbruce must have "sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case."[65] Dr. Imbruce may have the knowledge to describe the general physiology of oxygenation. Dr. Imbruce may have the knowledge regarding the various medical devices he invented. But Dr. Imbruce does not have the knowledge to do a failure analysis and make the very specific determination that a Terumo System 1 heart-lung bypass machine failed due to software issues that had never been identified by the manufacturer or—from the available information—any other user of the System 1.[66]

IHC argues the Terumo's argument and characterization of Dr. Imbruce's seeks "to impose an overly rigorous specialization requirement."[67] Even though Dr. Imbruce will not testify that "the System 1 or any component of the System 1 (including the operating software) is 'defective' in the sense of a product liability claim," he will offer very specific opinions (that the System 1 malfunctioned due to software issues) on a complicated piece of equipment. Offering this sort of opinion requires a certain degree of specialization. Dr. Imbruce does not have the necessary qualifications.

Therefore, Dr. Imbruce's opinion is excluded. Experts must be chosen with care. Impressive credentials are not enough if they do not address the specific questions in the case. An opinion of an unqualified expert amounts to little more than well-dressed speculation.

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[64] *Kumho*, 526 U.S. at 156.

[65] *Kumho*, 526 U.S. at 156 (internal quotation marks omitted).

[66] *See* Opposition at 27 (IHC admitting that Dr. Imbruce's software theory is novel: "Terumo's primary objections to the substance of Dr. Imbruce's opinion regarding the existence of a software flaw are that the specific software flaw acknowledged by Terumo would not impede user control of rpms and that the data log indicates that Mr. Garrett maintained the ability to increase and decrease rpms. However, the fact that Terumo only identified that particular aspect of the software flaw does not preclude the communications flaws identified by Dr. Imbruce manifesting themselves in the loss of control.").

[67] *Id.* at 22.

2. Even if he were qualified, Dr. Imbruce's opinion is not reliable.

Terumo gives several reasons that Dr. Imbruce failed to reliably apply failure analysis: Dr. Imbruce "lacked sufficient information for his analysis";[68] Dr. Imbruce "failed to perform a physical review or inspection of the System 1 and testing that would have confirmed or possibly rejected, his hypothesis that a software flaw caused the lack of forward flow";[69] and "Dr. Imbruce failed to apply a reliable process of elimination."[70]

In response, IHC recasts Dr. Imbruce's methodology:

> While he did not use those terms, it is readily apparent that the methodology employed by Dr. Imbruce in formulating his causation opinion is in substance that of "differential diagnosis" "differential analysis," or of "reasoning to the best inference": identifying potential causes and using the available information to eliminate potential causes in order to identify the probable cause.

However, Dr. Imbruce clearly states in his report, in "this case, failure analysis indicates that more likely than not . . . ." And even in his now-excluded affidavit, Dr. Imbruce states:

> As previously stated, I have used failure analysis to come to this conclusion. However, as is indicated by my report and by my prior deposition testimony, the type of failure analysis I have applied is not materials failure analysis . . . . Rather, the analysis I have applied in this case involves identifying the potential causes of the failure (in this case, the failure of effective arterial flow) and then evaluating whether the available evidence supports each cause and attempting thereby to eliminate possible causes and thus to identify the probable cause of the failure.[71]

IHC's effort to restyle Dr. Imbruce's methodology is not appropriate. The difference between the various methodologies is more than just terminological.

- Failure Analysis:
  [T]he principal stages of a failure investigation and analysis [include]: Collection of background data and selection of samples; preliminary examination of the failed part (visual examination and record keeping); nondestructive testing; mechanical testing (including hardness and

[68] Motion at 14.

[69] *Id.* at 15.

[70] *Id.* at 19.

[71] Imbruce Affidavit ¶ 14 at 4–5.

> toughness testing); selection, identification, preservation, and/or cleaning of all specimens; macroscopic examination and analysis (fracture surfaces, secondary cracks, and other surface phenomena); microscopic examination and analysis; selection and preparation of metallographic sections; examination and analysis of metallographic sections; determination of failure mechanism; chemical analysis (bulk, local, surface corrosion products, deposits or coatings, and electron microprobe analysis); analysis of fracture mechanics; testing under simulated service conditions (special tests); [and] analysis of all the evidence, formulation of conclusions, and writing the report (including recommendations).[72]

- Differential Diagnosis:
  > The determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings . . . . In the medical context, differential diagnosis is a common method of analysis, and federal courts have regularly found it reliable under *Daubert.* What is not so clear is whether "differential diagnosis" is an appropriate method when employed outside of the medical context.[73]

- Reasoning to the Best Inference:
  > Unlike a logical inference made by deduction where one proposition can be logically inferred from other known propositions, and unlike induction where a generalized conclusion can be inferred from a range of known particulars, inference to the best explanation—or "abductive inferences"—are drawn about a particular proposition or event by a process of eliminating all other possible conclusions to arrive at the most likely one, the one that best explains the available data.[74]

The differences between the methodologies are meaningful. IHC cannot decide after the disclosures, in response to a motion, to restyle the methodology that their expert consistently maintained he used. It is inefficient and does not conform to the requirement that an expert disclose "a complete statement of all opinions the witness will express and the basis and reasons for them."[75]

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[72] *Schipp v. General Motors Corp.*, 443 F. Supp. 2d 1023, 1028 (E.D. Ark. 2006) (punctuation normalized without signal).

[73] *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1237 (10th Cir. 2005) (internal citation and quotation marks omitted).

[74] *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1238 (10th Cir. 2005).

[75] Fed. R. Civ. P. 26(a)(2)(B)(i).

Nevertheless, ignoring the compelling arguments that Dr. Imbruce's opinion is not a reliable application of failure analysis,[76] which IHC has now abandoned, Dr. Imbruce fails to reliably apply reasoning to the best inference, IHC's new, superimposed methodology.

As Terumo correctly points out,[77] Dr. Imbruce has not identified independent evidence that the software flaw could have been the type that caused the lack of forward flow. The Tenth Circuit states in *Bitler*, "the inference to the best explanation must first be in the range of possible causes; there must be some independent evidence that the cause identified is of the type that could have been the cause."[78] Dr. Imbruce's theory is that there was a software flaw that

> allowed an inconsistence between what the readouts (and logically the machine log tied to the readouts) displayed and the actual speed at which the centrifugal pump was running. This indicates that this or another software flaw could result in a situation where the motor remains actually running at coast speed despite user efforts to increase the speed and despite readouts indicating higher motor speed settings.[79]

There is no independent evidence to support this theory. Dr. Imbruce has not tested this theory. Dr. Imbruce has identified no literature or any other evidence to support his theory. This does not satisfy the requirements for reliability. Therefore, Dr. Imbruce's opinion is excluded.

ORDER

IT IS HEREBY ORDERED that the Motion[80] is GRANTED.

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[76] *See* Motion at 13–20.

[77] Reply at 9–10.

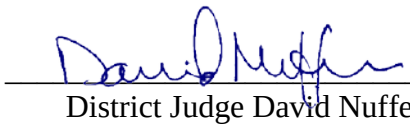
[78] *Bitler*, 400 F.3d at 1237.

[79] Imbruce's Report ¶ 11 at 2.

[80] Terumo Cardiovascular Systems Corporation's Motion to Exclude Richard Imbruce, docket no. 158, filed under seal May 15, 2017.

Signed August 7, 2017.

BY THE COURT



District Judge David Nuffer

United States District Court
for the
District of Utah
August 7, 2017

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2:12cv00998 DN-PMW

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